DEPARTMENT OF THE AIR FORCE
DETACHMENT 3, AIR FORCE INSTITUTE FOR OPERATIONAL HEALTH (AFIOH) (AFMC)
APO AP 96368-5213

24 April 2007

MEMORANDUM FOR US Naval Hospital – Okinawa
Attn: Pharmacy Department
PSC 482
FPO AP 96362

FROM: Det 3, AFIOH/CDO
Unit 5213
APO AP 96368-5213

SUBJECT: Consultative Letter, IOH-DO-BR-CL-2007-0023, Certification of a Mobile Isolation Chamber, Pharmacy Department, Lester U.S. Naval Hospital, Okinawa

1. **Executive Summary:** On 3 April 2007 personnel from Detachment 3, Air Force Institute for Operational Health (Det 3, AFIOH) completed a semi-annual certification of a Containment Technologies Group Mobile Isolation Chamber (MIC) at the Pharmacy Department, Lester Naval Hospital, Okinawa, Japan. This MIC was field certified in accordance with the Containment Technologies Group, Inc information manual for certification and ISO 14644-1/-2. A certification label was affixed to the front of the MIC. This consultative letter summarizes our findings and recommendations. The certification data is provided as Attachment 1.

2. **Background:** This MIC is used to work on pharmaceutical applications to include preparation of IVs and cytotoxic pharmaceuticals. The isolation unit is self contained with a 100% recirculated air through two High Efficiency Particulate Air (HEPA) Filters (supply and return). The MIC is designed to provide personnel, product and environmental protection from biohazardous particulate matter. Although the unit is self contained and operating under a negative pressure environment, it is not safe to use chemicals that may produce hazardous vapors. Chemical vapors are not affected by HEPA filters and will remain in the cabinet until it is opened and will then exhaust into the room. The following information listed below identifies key personnel contacted and certifying data used for the survey.

a. **Personnel Contacted (USN Hospital – Okinawa):**
(1) Mr. Edward Madden, Pharmacist
(2) MLC Harue Hanashiro, Industrial Hygiene Technician
(3) HM1 Chris Heplinger, NCOIC Medical Equipment Repair

b. **Certifying Personnel (Det 3, AFIOH):**
(1) Lt Col Victor Caravello, Chief, Occupational Health Services
(2) SSgt John Lacsina, Bioenvironmental Engineering Technician

c. **References:**

(1) Containment Technologies Group, Inc., Information Manual for Certification of the MIC, April 2005

Figure 1: Mobile Isolation Chamber (MIC)

Mobile Isolation Chamber

Model: MIC-Single
Serial Number: 0306-MPA-472)
Classification: ISO Class 5

This unit is located in the main Pharmacy, 2nd floor of Bldg 6000, room C215WE.

3. **Survey Protocol**: The operational certification protocol included the following parameters:

a. **Cleaning and Disinfecting the MIC Work Surface:** According to the manufacturer, the interior surfaces of the cabinet should be sanitized using a misting method of all internal surfaces. The manufacturer recommends using 70% alcohol or hydrogen peroxide. Further, it is recommended to alternate these disinfectants to reduce the possibility of organisms developing a resistance to the agents.

b. **Particle Count Testing Method:** Since the unit is self contained and all air is circulated through two HEPA filters, the environment inside the MIC should be clean and any aerosol generated in the unit should be captured by the filters. A particle counter is used to check the internal environment. The test grid of the MIC has five points – each corner and one point in the center. Each point is six inches from each wall and about six inches from the floor of the unit. Each point is tested three times and averaged. Statistical analysis is performed on the data to determine the correct ISO class.

c. **Recovery Testing:** When items are brought inside the MIC through the airlock, dirty air can easily enter the isolation chamber. The recovery check verifies the environment becomes particulate (contaminant) free quickly. The particle counter is positioned in front of the door and a basket is brought inside the unit through the airlock. Particle counts are obtained every minute until the unit is back to non-detectable levels.

d. **Magnehelic Gauge:** The magnehelic gauge, located on the top front of the unit, provides and indication of operating environment of the MIC. The gauge should normally indicate

the environment is under negative pressure (-0.2" of water). The gauge will also provide an indication of HEPA filter loading. As filters are loaded, the gauge reading will rise. According to the manufacturer, the magnehelic gauge should not read more than 1.5" of water. Similarly, if the gauge reading ever drops more than 0.4" of water from the normal operating position, there is a problem with your system and service is necessary.

e. **High Efficiency Particulate Air (HEPA) Filter Leak Test:** A leak test is performed to ensure the air passing through each of the two HEPA filters meets the particle penetration acceptance criteria of less than or equal to 0.01 % at any point. To evaluate filter leakage, an aerosol concentration (calculated based on the total cubic feet of air moved through the cabinet) is generated inside the enclosure and each HEPA filter is surveyed at the filter using a photometer. The return filter is surveyed by opening the top of the right side of the unit and taking face measurements. The supply filter is surveyed by opening the lower panel on the left side of the unit taking face measurements at the bottom of the filter (prior to entering the cabinet). Overlapping passes are made to ensure complete coverage. HEPA filters should only be replaced by personnel familiar with certification procedures. After filter replacement, and prior to resuming usage, the MIC must be re-certified.

4. **Findings and Discussion:**

a. **Cleaning and Disinfecting the Bench Work Surface:** Pharmacy personnel prepared the MIC for our arrival. The surface was cleaned with an appropriate disinfectant.

b. **Particle Count Testing Method:** All of the readings resulted with non-detectable particle concentrations. The statistical analysis resulted with the MIC meeting or exceeding ISO Class 5 Certification requirements. The grid profile and individual values are shown in Attachment 1.

c. **Recovery Testing:** The probe did not detect a particle concentration during the basket placement in the chamber. The test did not proceed beyond one minute. Test details are shown in Attachment 1.

d. **Magnehelic Gauge:** The magnehelic gauge reading was -0.25" of water. Therefore the MIC is operating as a negative pressure environment. Since there are valves that allow users to maintain a negative environment, it is important to note when the valves are adjusted and how they are adjusted to account for potential filter loading.

e. **High Efficiency Particulate Air (HEPA) Filter Leak Test:** The filter leak test was not performed. This test is not required for certification and will only be performed annually (every October).

5. **Conclusions**: The MIC is certified for six months. The next survey is scheduled for October 2007. A current certification label was affixed to the front of the MIC. Please note that the system should be re-certified out of cycle if any other significant changes are made.

6. We would like to thank all personnel involved for accommodating our survey schedule. If there are any questions, please contact SSgt Karl Lacsina at DSN 634-2634 or at karl.lacsina@kadena.af.mil.

VICTOR CARAVELLO, Lt Col, USAF, BSC
Chief, Occupational Health Services

Attachment:
Certification Data

cc:
USNH-OKI, Industrial Hygiene
USNH-OKI, Medical Equipment Repair

Certification Data

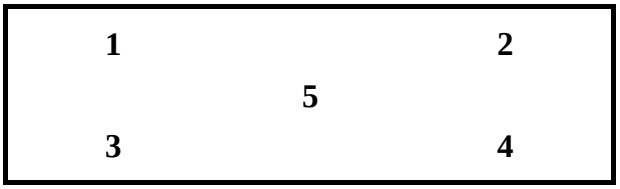
(1) **Date of Certification:** 3-Apr-07 Date Due Next Certification: 2-Oct-07

(2) **Type of Cabinet:** Containment Technologies Group, Inc -- Mobile Isolation Chamber
Model: MIC- Single Ser No. 0306-MPA-472
Location: Pharmacy, Bldg 6000, Rm C215WE

(3) **Particle Count Test:**

The particle count test determines the number of particles per cubic foot of air. The standard is to have less than 0.5 microns detected.

Measurements: Measurements were taken at 6" above the floor of the unit, 6" from each corner and one in the center. Each measurement was taken 3 times. The figure below shows the relative positions within the MIC.



a. Test Results:

				Averages
Position 1	0	1	0	0.333333
Position 2	0	2	1	1
Position 3	0	0	1	0.333333
Position 4	0	0	0	0
Position 5	0	0	0	0

Statistical Analysis of Data

Mean of the Averages	0.3333
Standard Deviation of the Avgs	0
Standard Error of the Mean:	0
Upper Confidence Limit:	0
Meets or Exceeds ISO Class:	5

(4) **Recovery Verification:**

This test checks to see how materials brought into the cabinet affect the particle count (contamination). The particle counter is placed inside the hood and a basket is introduced through the airlock and then into the MIC. Measurements are read at 1 and 2 minutes. This test is repeated 3 times.

	1	2	3	Average
a. Background counts outside the MIC:	25	17	15	**19.0000**

b. Count inside the MIC:

At: 1 min	2 min	Average
0	0	**0**
0	0	
0	0	

(5) **Magnehelic Gauge Reading:**

a. Gauge Reading: -0.25 Inches of water

b. Status: **Negative Pressure**